PATENT APPLICATION

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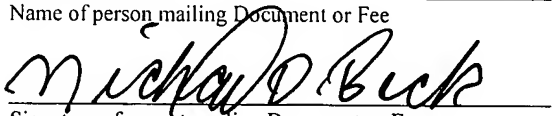

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TELEMETRIC TIBIAL TRAY

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TELEMETRIC TIBIAL TRAY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to the following U.S. Provisional Patent Applications: Serial No. 60/486,615, entitled "In Vivo Joint Space Measurement Device and Method", filed on July 11, 2003, and naming one of the co-inventors of the present application; Serial No. 60/486,762, entitled "In Vivo Joint Implant Cycle Counter", filed on July 11, 2003, and naming one of the co-inventors of the present application; and Serial No. 60/486,614, entitled "Orthopaedic Element With Self-Contained Data Storage", filed on July 11, 2003, and naming co-inventors of the present application. The disclosure of each of these provisional applications (60/486,615; 60/486,762; and 60/486,614) is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to orthopaedic components configured for implantation within a patient. In particular, the invention concerns systems and methods for evaluating loads within a joint space, and more particularly in the knee.

BACKGROUND OF THE INVENTION

Joint replacement surgery is quite common and enables many individuals to function normally when otherwise it would not be possible to do so. Artificial joints are normally composed of metallic and/or ceramic components that are fixed to existing bone.

Knee arthroplasty is a well known surgical procedure by which a diseased and/or damaged natural knee joint is replaced with a prosthetic knee joint. Typical knee prostheses include a femoral component, a patella component, a tibial tray or plateau, and a tibial bearing member. The femoral component generally includes a pair of laterally spaced apart condylar portions, the inferior or distal surfaces of which articulate with complementary condylar elements formed in a tibial bearing component.

In a properly functioning artificial knee joint, the condylar portions of the femoral component must slide and roll freely over the articulation surface formed by the condylar elements of the tibial bearing member. Natural friction within a replaced, artificial joint can lead to the development of wear debris in which minute particles of debris (e.g., metal or plastic from the prosthesis) become dislodged and migrate within the joint. The phenomenon of wear debris within artificial joints is a serious problem that can inhibit the proper mechanical functioning of the joint. Moreover, wear debris can lead to osteolysis and bone deterioration. When wear debris develops within an artificial joint, surgical removal of the debris or subsequent replacement of the artificial joint is often necessary.

During normal usage of a properly implanted prosthetic knee joint, load and stress are placed on the tibial bearing member. The tibial bearing member is typically made of an ultrahigh molecular weight polyethylene (UHMWPE), and friction, continuous cycling and stress can cause some erosion and/or fracture of the tibial bearing member, thus leading to wear debris. The risk of wear debris can be even greater during malalignment of an artificial knee joint, which can result from normal usage or from imperfect and/or inaccurate implantation of the prosthesis within a patient. During malalignment the load upon the tibial bearing member is not evenly distributed. Instead, excess load is placed on certain areas of the tibial bearing member. This uneven distribution of load (or edge loading) can accelerate the development of wear debris. Contact stresses on the tibial bearing member increase substantially with malalignment of the joint, thus increasing the risk that wear debris will develop when a prosthetic knee joint is subjected to malalignment conditions.

Joint replacement surgery obviously requires a tremendous degree of precision to ensure that prosthetic components are properly sized, implanted, and aligned. Imperfect sizing, implantation and alignment can lead to inadequate performance of the knee joint as well as to the presence of high contact stresses in certain areas of the prosthesis, thus leading to the possible development of wear debris.

The anatomy of patients who undergo knee arthroplasty is widely variable and can lead to difficulty in matching the standard sized prosthetic components that form a prosthetic joint. Many prosthetic components are manufactured such that similarly sized components must be used together and implanted within a patient when replacing a natural joint. That is, the femoral component, tibial bearing member, and tibial plateau that form the artificial knee joint must normally be of a matched size. If the components are not size-matched, inappropriate edge loading may develop and accelerate wear.

FIG. 1 illustrates three components found in a typical knee joint prosthesis **10**. A femoral component **12** includes a superior surface **14** which is mountable within the distal end of a patient's femur and an inferior articulation surface **16**. The articulation surface **16** includes adjacent condyles **18**. The knee prosthesis **10** also includes a tibial tray or plateau **20** which includes a distally extending stem **22** that is mountable within the tibia of a patient. The proximal end of the tibial tray **20** includes a recessed region **24** within which a tibial bearing member **26** is mounted in a mechanical fit.

Tibial bearing member **26** includes a distal surface **30** mountable within the recessed region **24** of the proximal end of a tibial tray**20**plateau **24**. The proximal face of tibial bearing member **26** forms articulation surfaces **28** that engage and articulate with the articulation surfaces **16** of femoral component **12**. The articulation surfaces **28** of the tibial bearing member **26** are configured to correspond to the condyles **18** of the femoral component **12**.

The articulation surface **16** of femoral component **12** and the articulation surfaces **28** of tibial bearing member **26** are configured such that the contact area is maximized. The greatest contact area is achieved in conditions of perfect alignment throughout the range of motion of the knee joint, and in certain conditions of malalignment, including varus-valgus lift and internal-external rotation. The ability to achieve a large contact area between the articulating surfaces is significant because contact stress on the prosthesis components is minimized, particularly the tibial bearing member. Most standard tibial bearing members are manufactured of polymeric materials, such as ultra-high molecular

weight polyethylene (UHMWPE), ceramic or metal. Where loads are unevenly distributed or concentrated across the tibial bearing member during use of an artificial knee joint, edge loading can develop. Edge loading leads to the development of higher contact stresses in certain parts of the prosthesis which, in turn, can cause wear of the articulating surfaces. Debris resulting from this wear can develop within the joint, sometimes leading to osteolysis.

More significantly, undue bearing wear can result in conditions requiring that the joint endoprosthesis be removed and replaced in a revision procedure. Accordingly, early determination of unacceptable wear conditions is critical. Misalignment of the joint prosthesis components can be detected during the implantation procedure and during rehabilitation of the new joint. Various measurements and templates can evaluate proper positioning and spacing of the components.

Another important indicator of proper or improper alignment is the distribution and transfer of loads across the prosthesis. In particular, loads experienced by the tibial tray **20** can provide the earliest indication of bad joint "fit". In order to evaluate these loads, telemetric implant components have been developed, such as the dual tray telemetric implant described in U.S. Patent No. 5,360,016 ("016 Patent"), the disclosure of which is incorporated herein by reference. A force transducer is incorporated into the proximal tibial component of the implant. The force transducer uses strain gages to generate output signals indicative of force measurement data that can be used to assess pressure differences across the surface of the tibial tray which may be indicative of an improperly aligned implant.

Another telemetric implant is embodied in a tibial component **40** depicted in **FIGS. 2** and **3**. The tibial component **40** includes a stem **42** configured to be engaged within the tibia. A tibial tray **44** is mounted on the stem, and includes a cover plate **46** that is directly attached to the stem. A lower plate **48** is mounted on the cover plate, while an upper plate **50** is supported on the lower plate by a plurality of support posts **52**. As best seen in **FIG. 3**, the lower plate **48** includes

a perimeter wall **54** configured to engage the cover plate **46**. Fasteners (not shown) are used to fasten the two plates together.

The lower plate defines a plurality of transducer cavities **56**, each corresponding to a support post. The base of each cavity defines a diaphragm **63** to which a corresponding support post **52** is attached or integrally formed. The support posts are preferably integral with the lower plate **48** and the upper plate **50** but are configured to separate the two plates by a gap **53**. Load applied to the upper plate **50** is transmitted through the support posts **52** to the integral diaphragms **63** which flex in relation to the transmitted load.

In order to measure the deflection of these diaphragms, a force sensing element is disposed within each transducer cavity. More specifically, the force sensing elements include an array of strain gages that are affixed to the diaphragm at the base of each transducer cavity **63**. As shown in **FIG. 3**, each strain gage array includes four radially inner strain gages **67** and four radially outer gages **69** disposed at the four compass points around the cavity. More specifically, the strain gages are arranged in planes that are at 90 degrees or 180 degrees to the sagittal and/or lateral planes of the knee joint prosthesi.

The strain gages include wiring **71** that passes through wiring channels **60** and **61** to a centrally located circuitry cavity **58**. A processing circuit board **73** is disposed within this cavity and includes electrical components and/or integrated circuits adapted to process the output of the strain gages and facilitate translation of that output into load information. In some implants, such as the force transducer disclosed in the '016 Patent incorporated above, the circuit board **73** serves to condition the strain gage signals and to provide a wiring harness for connection to an external processor or computer. In other implants, the circuit board **73** prepares the strain gage signals for transmission by a transmission device. In some implants, the circuit board includes a telemetry device and a power supply. In other implants, the stem **42** (**FIG. 2**) carries a telemetry device **75** and associated power source **77** adapted to transmit the strain gage output signals to an external processor where the signals are evaluated.

In the telemetric tibial component **40** shown in **FIG. 3**, a no-load post **65** projects from the diaphragm **63** between the inner strain gages **67**. It can be appreciated that the no load posts **65** are essentially co-linear with the support posts **52**, although the two sets of posts reside on opposite sides of the diaphragm **63** of each transducer cavity **56**. The no-load posts are believed to promote a circumferentially symmetric strain pattern within each cavity.

The introduction of telemetric implants has provided a means for evaluating the loads actually experienced by an endoprosthesis. This evaluation can occur in real-time as the joint is exercised and loaded. However, since the primary function of the implant is to serve as a prosthetic joint, and not simply as a data transmission device, the implant must be able to withstand joint loads without failure. Load is transmitted from the femur to the tibia through the large articulating surface areas of the condylar surfaces **16** and the bearing surfaces **28**. However, once the load reaches the tibial tray, such as the tibial tray **44**, the force is transmitted through four support posts **52** into the tibia. Therefore, it can be appreciated that the strength of these posts is critical to the strength of the implant.

In conflict with need for structural strength is the need to generate sufficient strain in the diaphragms **63** such that a measurable strain differential may be detected between the strain gages **67** and **69**. The ability to accurately measure the forces transmitted across the joint space is enhanced as the magnitude of the strain differential increases. The trade-off for a stronger implant has been a reduction in diaphragm strain and a sacrifice in accuracy of the load measurement. The introduction of the no-load posts **65** is an effort to recapture some accuracy in the load measurement capabilities of the strain gage arrays. There remains room for improvement in both the strength of the telemetric implant component as well as the ability of the transducer component to provide a true measure of the loads transmitted across the joint.

SUMMARY OF THE INVENTION

The telemetric tibial tray of the present invention provides an optimum balance of implant strength and accuracy in load measurement. In accordance with one embodiment of the invention, the cross-sectional area of the support posts is increased over the prior art devices. Moreover, in lieu of the square cross-section of the prior art support posts, the support posts in the present invention are circular, which maximizes the load-bearing area of the posts without sacrificing flex responsiveness of the load diaphragm to which the posts are attached.

In another feature of the invention, the no-load post is eliminated so that the cavity-side face of the load diaphragm is featureless. Removing the no-load posts eliminates stress risers at the junction between the no-load posts and the diaphragms and significantly reduces the risk of fracture at the base of the support posts.

In addition, removing the no-load posts allows repositioning of the strain gage array from the pattern employed in the prior art. It has been found that the radial strain pattern across the load diaphragm exhibits significant micro-strain behavior at the center of the diaphragm. Removing the no-load posts allows placement of the radially inboard strain gages as close to the center of the diaphragm as possible. At each circumferential position, there is more room for the radially outermost strain gage so that the two strain gages at each circumferential position yield a more accurate differential strain reading, which translates into a more accurate measure of the diaphragm strain.

The radial position of the inner and outer strain gages is also calibrated according to the micro-strain response of the transducer cavity diaphragm to load. In one aspect of the invention, the inner strain gage is positioned to span the radial location at which the maximum positive micro-strain occurs. The outer strain gage is positioned at a radial location between the zero crossing point and the outer wall of the cylindrical transducer cavity. In a more specific aspect, the outer strain gage is positioned to span the radial location of the maximum negative micro-strain response of the diaphragm. These optimized locations

produce the greatest differential strain value, which leads to greater strain sensitivity of the force measurement features of the invention.

Another aspect of the strain gage pattern diverges from the compass point arrangement of the prior art telemetric implants. Rather than align the radial strain gages in planes parallel to the sagittal and lateral planes through the joint, the strain gages of the present invention are rotated at 45 degrees. It has been found that this orientation of the radial strain gages increases the strain sensitivity of the transducer component, especially when the joint is flexed or extended.

A further improvement provided by the present invention is in the location of the wiring channels in the tibial tray. The wiring channels, although necessary for connection of the strain gage wiring to the central circuit board, disrupt the transducer cavities and produce non-uniform strain patterns across the load diaphragm. In accordance with one feature of the invention, the wiring channels intersecting each transducer cavity is at a 45 degree angle relative to the sagittal and lateral planes. It has been found that this positioning of the wiring channels also increases the strain sensitivity of the transducer.

It is one object of the present invention to provide a telemetric tibial tray that has increased strength characteristics over prior telemetric components. Another object is to increase the strain sensitivity of the telemetric component over prior devices. These and other objects, as well as specific benefits, of the present invention will be appreciated upon consideration of the written description and accompanying figures.

DESCRIPTION OF THE FIGURES

FIG. 1 is an exploded perspective view of the components of a knee prosthesis.

FIG. 2 is a side view of a tibial component of a knee prosthesis.

FIG. 3 is a bottom view of a lower transducer plate forming part of the tibial component shown in **FIG. 2**.

FIG. 4 is a bottom view of a lower transducer plate for a telemetric tibial tray in accordance with one embodiment of the present invention.

FIG. 5 is a partial cross-sectional view of the lower transducer plate shown in **FIG. 4**.

FIG. 6 is a graph of micro-strain as a function of radial distance in a transducer cavity of the plate shown in **FIG. 4**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purpose of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and described in the following written specification. It is understood that no limitation to the scope of the invention is thereby intended. It is further understood that the present invention includes any alterations and modifications to the illustrated embodiments and includes further applications of the principles of the invention as would normally occur to one skilled in the art to which this invention pertains.

As shown in **FIG. 3**, the lower transducer plate **48** of prior telemetric tibial trays utilizes support posts **52** that are square in cross-section. These support posts typically have a dimension of about 2.5 mm on each side. Each support post is integral with the load diaphragm **63** and is aligned with the no-load post **65** projecting into the transducer cavity. The no-load posts produce stress risers at the junction with the load diaphragm. The strain pattern across the diaphragm is disrupted by the presence of the no-load posts.

Moreover, the posts **65** limit the radial space available in the cavity **56** for placing the radial strain gages **67**, **69**. In prior devices, two strain gages are placed diametrically opposite each other, as reflected in the **'016** Patent incorporated above. In later devices, two strain gages have been placed along each radial extent to measure the differential strain at different circumferential positions around the diaphragm. The presence of the no-load posts **65** in these prior devices limits the space available for the radial strain gage pairs.

In the prior devices, such as the tibial component **40** illustrated in **FIG. 3**, the strain gage pairs are aligned along the compass points. More succinctly, the strain gages are positioned in planes that are parallel with the sagittal and lateral planes of the joint. Similarly, the wiring channels **60**, **61** of the prior device **40** are also aligned with the sagittal and lateral planes. The wiring channels interrupt the transducer cavity and disrupt the strain sensitivity at that intersection.

The present invention provides significant improvements over the tibial component **40** and addresses certain limitations of this component discussed above. Referring to **FIGS. 4** and **5**, a lower plate **81** is provided as part of a telemetric tibial tray. The lower plate **81** and an integral upper plate **79** (**FIG. 5**) can be substituted for the like components of the tibial tray **44** shown in **FIG. 2**. Thus, the lower plate **81** defines a perimeter wall **82** that is configured to engage the cover plate **46** so that the cover plate can shield the electrical components carried by the lower plate. The upper plate **79** includes a recess **80** configured to receive the tibial bearing member **26** depicted in **FIG. 1**.

As with the prior art devices, the lower plate **81** includes a plurality of cylindrical transducer cavities **83** and a centrally located circuitry cavity **84**. The upper and lower plates are integrally attached by four support posts **86** projecting from a circular load diaphragm **88** in each transducer cavity. As understood, the diaphragms **88** flex when subjected to forces transmitted through the support posts **86**. However, unlike the prior art, the support posts have a circular cross-section, as best seen in **FIG. 4**. Moreover, the cross-sectional area of these support posts **86** is significantly increased over the support posts of the prior art, such as the square posts shown in **FIG. 3**. In the preferred embodiment of the invention, the support posts **86** have a diameter of about 5.0 mm. The cross-sectional area of these posts is about $20mm^2$, which is over three times larger than the cross-sectional area ($6.25mm^2$) of the prior devices. This significantly greater cross-sectional area means that the support posts **86** have greater load bearing capacity with a longer fatigue life than the prior devices. In a preferred embodiment of the invention, the diameter of the support posts is about 1/3 the diameter of the transducer cavity.

In a further feature of the invention, the load diaphragm **88** does not include a no-load post at the center of the diaphragm. Eliminating the no-load posts found in the prior devices (see **FIG. 3**) eliminates the stress risers and the potential locus for fatigue that accompanies those load posts. Moreover, removing the no-load posts frees the center of the diaphragm for an optimum placement of radial strain gages around the transducer cavities **83**.

Turning to the graph of **FIG. 6**, it can be seen that the micro-strain as a function of radial distance exhibits a high response at the center of the load diaphragm **88**. The micro-strain remains at this high level for about half the radial distance to the perimeter of the transducer cavity and exhibits a positive maximum value at a radial location M^+ offset from the center of the diaphragm. The zero-crossing represents the point at which the micro-strain reverses sign from a positive magnitude to a negative magnitude. The zero crossing point **Z** for the micro-strain is nearer the radial edge of the cavity. The micro-strain response of the diaphragm also exhibits a negative maximum value point M^- between the zero crossing point and the outer wall **89** of the cylindrical cavity. This strain graph provides a guideline for optimum placement of the force sensing elements within the cavities, or more particularly the radial strain gages, namely the inner gages **90** and radially outer gages **91**.

As is known in the art, the strain gage array measures differential strain across the diaphragm, which can then be translated directly into a measure of the forces imposed on the diaphragm as the knee prosthesis is loaded. Depending upon the arrangement of the array, the measured strains can be used to calculate the load imposed on the tibial tray, including its magnitude, direction and location. These calculations can be made in an external processor, such as a computer, upon receiving the data transmitted form the telemetric implant in a known manner. As is known in the art, providing a cylindrical transducer cavity and circular load diaphragm allows placement of the strain gages in a circumferential pattern about the center of the diaphragm to evaluate the radial differential strain across the diaphragm.

Increasing the strain sensitivity of the strain gage array will produce a more accurate measure of the differential strain at various points around the load diaphragm. It has been found in accordance with the present invention that placing the radially inner strain gages **90** close to the center of the diaphragm increases the strain sensitivity of the gage array. In a preferred embodiment, the inner gages are positioned to span the maximum micro-strain point M^+, which in

a specific embodiment is within 2.5 mm of center. Removal of the no-load post allows this more radially inboard position for the inner strain gage.

In addition, the present invention contemplates positioning the outer strain gages as close as possible to or immediately adjacent the outer wall **89** (**FIG. 5**) of the cylindrical cavity **83**. With this position, the outer gages **91** will be positioned beyond the zero crossing point **Z** for the micro-strain across the diaphragm. Preferably, the outer gage is positioned to span the negative maximum micro-strain point $\mathbf{M}^{-}$. This placement of the inner and outer strain gages **90**, **91** produces the largest differential strain, and consequently the greatest strain sensitivity. As an additional improvement, the diameter of the transducer cavities is increased from the prior art devices. Specifically, the diameter is increased from 13.4 mm to about 15.0 mm. This larger diameter provides more radial space for placement of the outer strain gage **91**, which assures that the outer gage will be well beyond the zero-crossing for the micro-strain, as reflected in the graph of **FIG. 6**. The larger diameter transducer cavity consequently yields greater differential strain values, which improves the accuracy of the load measurements.

The preferred embodiment of the invention yields even greater improvements in load measurement accuracy by optimizing the orientation of the strain gage arrays. It has been found that rotating the diametrically opposed inner/outer gage pairs by 45 degrees further increases measurement sensitivity. Thus, as shown in **FIG. 4**, the inner and outer gages **90**, **91**, respectively, are arranged at a 45 degree angle relative to the sagittal and lateral planes. Rotating the position of the radial strain gage pairs increases the differential strain measured between the inner and outer gages, relative to the conventional placed gages of the prior art. Again, increases in differential strain translate directly into more accurate load measurements in each load diaphragm.

Additional improvement is realized by orienting the strain gages at a 45 degree angle relative to the wiring channels. In one embodiment of the invention, the strain gages **90, 91** are oriented as shown in **FIG. 4**, while the wiring channels **60** are oriented as shown in **FIG. 3**. In other words, the wiring

channels are arranged at 90 or 180 degrees relative to the sagittal plane for the joint or prosthesis, while the strain gages **90, 91** are oriented at 45 or 135 degrees to the same plane. Thus, with this specific embodiment, no strain gage is aligned with the interface between a transducer cavity and a wiring channel.

In another aspect of the invention, arrangement of the wiring channels was also found to contribute to the strain sensitivity of the telemetric tibial tray. The wiring channels **85** provide a path for the strain gage wiring to connect to the circuit board **93** disposed within the central cavity **84**. (Note that the wires are not depicted within the channels **85** in **FIG. 4** for clarity). It can be appreciated that the intersection of a wiring channel with the transducer cavity creates a localized disruption in the strain pattern across the diaphragm **88**; however, the wiring channels are necessary (absent the cost-prohibitive approach of burying the wires within the body of the lower plate **81**). The present invention contemplates optimum positioning of the wiring channels at 45 degrees to the sagittal and lateral planes, as illustrated in **FIG. 4**. This orientation of the wiring channel produces greater differential strains than the prior conventional channel placement.

With the wiring channel arrangement shown in **FIG. 4**, it is preferable that the strain gages be oriented at an offset angle relative to the channels. In other words, it is preferable that no strain gage be aligned with the intersection between a wiring channel and a corresponding transducer cavity. Thus, in a specific embodiment, the wiring channels **85** are angularly oriented as shown in **FIG. 4** at a 45 or 135 degree angle relative to the sagittal plane, while the strain gages can be arranged like the gages **67, 69** shown in **FIG. 3** at 0 or 180 degrees relative to the same plane. In certain alternatives, improvements in differential strain sensitivity may still be accomplished if the strain gages and wiring channels are both oriented at the 45 and 135 degree angles.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same should be considered as illustrative and not restrictive in character. It is understood that only the preferred embodiments have been presented and that all changes, modifications and

further applications that come within the spirit of the invention are desired to be protected.